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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/623,431

07/18/2003

Jay D. Kranzler

CYPR 100 CIP CON

4067

7278

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12/24/2008

DARBY & DARBY P.C.

P.O. BOX 770

Church Street Station

New York, NY 10008-0770

EXAMINER

HUGHES, ALICIA R

ART UNIT

PAPER NUMBER

1614

MAIL DATE

DELIVERY MODE

12/24/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Advisory Action Before the Filing of an Appeal Brief	Application No. 10/623,431	Applicant(s) KRANZLER ET AL.	
	Examiner ALICIA R. HUGHES	Art Unit 1614	

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 05 November 2008 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE.

1. ☐ The reply was filed after a final rejection, but prior to or on the same day as filing a Notice of Appeal. To avoid abandonment of this application, applicant must timely file one of the following replies: (1) an amendment, affidavit, or other evidence, which places the application in condition for allowance; (2) a Notice of Appeal (with appeal fee) in compliance with 37 CFR 41.31; or (3) a Request for Continued Examination (RCE) in compliance with 37 CFR 1.114. The reply must be filed within one of the following time periods:

- a) ☐ The period for reply expires _____ months from the mailing date of the final rejection.
- b) ☒ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.

Examiner Note: If box 1 is checked, check either box (a) or (b). ONLY CHECK BOX (b) WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

NOTICE OF APPEAL

2. ☐ The Notice of Appeal was filed on _____. A brief in compliance with 37 CFR 41.37 must be filed within two months of the date of filing the Notice of Appeal (37 CFR 41.37(a)), or any extension thereof (37 CFR 41.37(e)), to avoid dismissal of the appeal. Since a Notice of Appeal has been filed, any reply must be filed within the time period set forth in 37 CFR 41.37(a).

AMENDMENTS

3. ☒ The proposed amendment(s) filed after a final rejection, but prior to the date of filing a brief, will not be entered because
- (a) ☒ They raise new issues that would require further consideration and/or search (see NOTE below);
- (b) ☐ They raise the issue of new matter (see NOTE below);
- (c) ☒ They are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
- (d) ☐ They present additional claims without canceling a corresponding number of finally rejected claims.

NOTE: See Continuation Sheet. (See 37 CFR 1.116 and 41.33(a)).

4. ☐ The amendments are not in compliance with 37 CFR 1.121. See attached Notice of Non-Compliant Amendment (PTOL-324).
5. ☐ Applicant's reply has overcome the following rejection(s): _____.
6. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
7. ☒ For purposes of appeal, the proposed amendment(s): a) ☒ will not be entered, or b) ☐ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.
- The status of the claim(s) is (or will be) as follows:
- Claim(s) allowed: _____.
- Claim(s) objected to: _____.
- Claim(s) rejected: 99,101,109,111,119 and 121.
- Claim(s) withdrawn from consideration: 100,102-108,110,112-118,120 and 122-128.

AFFIDAVIT OR OTHER EVIDENCE

8. ☐ The affidavit or other evidence filed after a final action, but before or on the date of filing a Notice of Appeal will not be entered because applicant failed to provide a showing of good and sufficient reasons why the affidavit or other evidence is necessary and was not earlier presented. See 37 CFR 1.116(e).
9. ☐ The affidavit or other evidence filed after the date of filing a Notice of Appeal, but prior to the date of filing a brief, will not be entered because the affidavit or other evidence failed to overcome all rejections under appeal and/or appellant fails to provide a showing of good and sufficient reasons why it is necessary and was not earlier presented. See 37 CFR 41.33(d)(1).
10. ☐ The affidavit or other evidence is entered. An explanation of the status of the claims after entry is below or attached.

REQUEST FOR RECONSIDERATION/OTHER

11. ☒ The request for reconsideration has been considered but does NOT place the application in condition for allowance because:
See Continuation Sheet.
12. ☐ Note the attached Information *Disclosure Statement*(s). (PTO/SB/08) Paper No(s). _____
13. ☐ Other: _____.

/Raymond J Henley III/
 Primary Examiner, Art Unit 1614

Continuation of 3. NOTE: Applicants have changed the scope of the claims by amending the claim language to read "the method consisting essentially of" as opposed to the more open claim language comprising and further, have omitted nine of the ten contemplated drugs for combination therapy that were initially contemplated. The effect of these amendments would be the requirement for a new, more concentrated search.

Continuation of 11. does NOT place the application in condition for allowance because: Loder et al teach that chronic fatigue syndrome, fibromyalgia and perceptive pain associated therewith and depressed mood as known disorders of neurological origin treatable with a drug that "is a compound which inhibits both noradrenaline and serotonin reuptake" and more specifically, milnacipran accompanied by either L-phenylalanine or tyrosine. At the time the instant invention was contemplated, it was well-understood in the art that milnacipran is an antidepressant often preferred for its "equipotent double inhibition both noradrenaline and serotonin reuptake and its lack of affinity for neurotransmitter receptors."

Loder et al also teach that as an alternative to usage of a compound that inhibits both noradrenaline and serotonin reuptake, a compound that inhibits both noradrenaline and dopamine reuptake, such as bupropion, may be used to treat fibromyalgia and chronic fatigue syndrome.

Seehra et al teach the administration of pregabalin as effective in the treatment of pain, fibromyalgia and chronic fatigue syndrome, and that it can be used in combination with other drugs effective in treatment of the same.

It is well-understood that combining compounds known to individually treat a known disease or disorder would obviously treat the same disease/disorder when combined. See *In re Kerkhoven*. Therefore, the combination of an effective amount of milnacipran with pregabalin to treat pain, fibromyalgia and chronic fatigue syndrome, for example, would have a reasonable expectation of success.